

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :  
Ryoichi NAGATA : Attn: BOX PCT  
Serial No. [NEW] : Docket No. 2001-1906A  
Filed December 28, 2001 :

PREPARATION FOR NASAL ABSORPTION :  
OF INSULIN  
[Corresponding to PCT/JP01/03642  
Filed April 26, 2001]

THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEE FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975.

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents,  
Washington, DC 20231

Sir:

In the interest of reducing PTO filing fees, please amend the present application as follows:

IN THE CLAIMS:

*Please amend claims 3-8 and 10 as follows:*

3. (Amended) The formulation according to Claim 1, in which the porous, spherical calcium carbonate has a particle diameter in the substantial range of 18-115  $\mu\text{m}$ .

4. (Amended) The formulation according to Claim 1, in which the porous, spherical calcium carbonate has a particle diameter in the substantial range of 20-32  $\mu\text{m}$ .

5. (Amended) The formulation according to Claim 1, in which the porous, spherical calcium carbonate has a particle diameter in the substantial range of 20-32  $\mu\text{m}$ , and a median particle diameter of 22  $\mu\text{m}$  or greater and less than 30  $\mu\text{m}$

ATTACHMENT E

6. **(Amended)** The formulation according to Claim 1, in which the porous, spherical calcium carbonate has a particle diameter in the range of 20-32  $\mu\text{m}$ .

7. **(Amended)** The formulation according to Claim 1, in which the insulin content of the component composed of insulin and porous, spherical calcium carbonate is 0.1-50% by weight based on the total weight of the component.

8. **(Amended)** The formulation according to Claim 1, in which the porous, spherical calcium carbonate has a relative surface area of 1.5  $\text{m}^2/\text{g}$  or greater.

10. **(Amended)** The formulation according to Claim 1, in which the insulin content of the component composed of insulin and calcium carbonate is 0.1-50% by weight based on the total weight of the component.

**REMARKS**


The above amendment is presented to eliminate multiple dependent claims, thereby reducing PTO filing fees.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is entitled "**Version with Markings to Show Changes Made**".

Favorable action on the merits is now requested.

Respectfully submitted,

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December 28, 2001

## VERSION WITH MARKINGS TO SHOW CHANGES MADE

### IN THE CLAIMS:

*Claims 3-8 and 10 have been amended as follows:*

3. (Amended) The formulation according to Claim 1 [or 2], in which the porous, spherical calcium carbonate has a particle diameter in the substantial range of 18-115  $\mu\text{m}$ .
4. (Amended) The formulation according to Claim 1 [or 2], in which the porous, spherical calcium carbonate has a particle diameter in the substantial range of 20-32  $\mu\text{m}$ .
5. (Amended) The formulation according to Claim 1 [or 2], in which the porous, spherical calcium carbonate has a particle diameter in the substantial range of 20-32  $\mu\text{m}$ , and a median particle diameter of 22  $\mu\text{m}$  or greater and less than 30  $\mu\text{m}$ .
6. (Amended) The formulation according to Claim 1 [or 2], in which the porous, spherical calcium carbonate has a particle diameter in the range of 20-32  $\mu\text{m}$ .
7. (Amended) The formulation according to [any of Claims 1-6] Claim 1, in which the insulin content of the component composed of insulin and porous, spherical calcium carbonate is 0.1-50% by weight based on the total weight of the component.
8. (Amended) The formulation according to [any of Claims 1-7] Claim 1, in which the porous, spherical calcium carbonate has a relative surface area of 1.5  $\text{m}^2/\text{g}$  or greater.
10. (Amended) The formulation according to [any of Claims 1-9] Claim 1, in which the insulin content of the component composed of insulin and calcium carbonate is 0.1-50% by weight based on the total weight of the component.